

***Section XV: Projects Conducted by Midshipmen
(Research, Capstone, and Design)***

15.1 At the U.S. Naval Academy, midshipmen participate in a variety of project-oriented experiences as part of the academic curriculum. These include, but are not limited to, research project courses, Trident Scholar Program projects, capstone project investigations, and design projects.

a. In general, the investigations conducted within the midshipman research project courses and the Trident Scholar Program meet the definition of research (as provided in Section II of this policies and procedures manual), while the investigations in the capstone and design venues do not meet the referenced research definition. As such, the latter are more properly described as classroom- or laboratory-based projects or demonstrations with the student efforts focused on investigating or revalidating known concepts and/or principles.

b. Classroom- or laboratory-based projects or demonstrations are generally not reviewed by the Academy's IRB. An exception, however, is when the project directly or indirectly involves human subjects as participants in the project or the project uses data about human subjects. In these cases, the policies and procedures defined in this manual apply, and a project protocol must be submitted to the Academy's IRB prior to any activity on the project. After the project has been favorably reviewed by the Academy's IRB with respect to the role of the human subjects and the collection and use of any data about human subjects, and after the principal investigator has been notified of the project approval by the Superintendent, participant enrollment, distribution of informed consent forms, analysis of existing datasets, and data collection activities on the project may begin.

15.2 Midshipman research projects and the Trident Scholar Program projects are managed at the Naval Academy through the academic curriculum (as xx495-496 courses or as xx58# courses, respectively). In the project courses and in the Trident Scholar projects, the midshipman (an undergraduate student) is the lead investigator and he/she is mentored by one or more USNA faculty members. For the purposes of any review by the Chair of the Academy's IRB, by the Academy's IRB, or by the Academy's HRPP office, the midshipman and the faculty mentor are co-investigators.

15.3 Midshipman and Faculty Responsibilities

a. When human subjects or data about human subjects are used in classroom- or laboratory-based projects or demonstrations, **the course instructor must** satisfy the following requirements:

1. Submit a research protocol for review by the Academy's IRB and subsequent approval by the Academy's Superintendent. (Additional information on this submission is available in Section X of this policies and procedures manual.)

2. Obtain written notification of the results of the Academy's IRB review of and the subsequent approval decision on the protocol by the Superintendent before beginning any participant selection, informed consent distribution, dataset analysis, or data collection activity on the project and before distributing any human subject datasets to the students enrolled in the course.
3. Complete all required human subject research training and coordinate the training of his/her students. (Additional guidance on the education and training of persons conducting human subject research or working with data about human subjects can be found in Section V of this policies and procedures manual.)
4. Comply with all applicable federal, state and local laws, DoN regulations, and SECNAV and USNA instructions that relate to the protection of the human subjects and the data about them. Failure of the course instructor to comply with the requirements to safeguard the data about human subjects constitutes non-compliance and may constitute research misconduct. (Additional information about these two topics can be found in Section XX of this policies and procedures manual.)
5. Inform the students enrolled in the course of the applicable policies of the Academy's IRB and the Academy's Human Research Protection Program, as described in this policies and procedures manual, and in related USNA and SECNAV instructions, directives and notices.
6. Discuss research ethics, in the context of human subjects and the proper handling of the data about human subjects, with the student-researchers in the course.
7. Inform the midshipmen at USNA and/or the midshipman candidates at the Naval Academy Preparatory School, as applicable to the student's involvement in or connection to the project, about the federal laws, DoN regulations, SECNAV instructions, and USNA instructions in effect to protect and safeguard human subjects participating in curriculum activities and research studies. As part of this briefing, the instructor should advise the students that any misuse or unauthorized disclosure of the data can result in both civil and criminal penalties, and in administrative penalties at USNA.
8. Monitor his/her students to confirm that their use of the human subject data is proper and within the parameters of the approved project, that they are adequately safeguarding and protecting the confidentiality of the data, and that all data collection has occurred within the authorized timelines of the project.
9. Verify that each student has properly de-identified the data and that no student has retained the "key" that allows the dataset to be re-identified.

10. Validate to his/her immediate supervisor, at the conclusion of the project, that each student in the course has (a) deleted all electronic copies of the human subject data from his/her personal or laptop computer, shared network computer, and/or data storage devices and (b) properly shredded all hardcopies of the identified data collected by or distributed to him/her during the project.

11. Validate to his/her immediate supervisor, at the conclusion of the project, that **all** hard and electronic copies of the data used and generated in a human subject project, survey or focus group, have been properly destroyed when the destruction of the human subject data had been required as a condition of the support for the project by the Academy's IRB and the subsequent approval of the project by the Superintendent.

b. When human subjects or data about human subjects are used in research projects or Trident Scholar Program projects conducted by midshipmen, the faculty mentor(s) for the student-researcher **must** satisfy the following requirements:

1. Inform the student-researcher of the applicable policies of the Academy's IRB and the Academy's Human Research Protection Program, as described in this polices and procedures manual, and in related USNA instructions, directives and notices.

2. Discuss research ethics, in the context of human subjects and the proper handling of data about human subjects, with the student-researcher.

3. Inform the student-researcher about the federal laws, DoN regulations, SECNAV instructions, and USNA instructions in effect to protect and safeguard human subjects participating in curriculum activities and research studies. As part of this briefing, the instructor should advise the student-researcher that any misuse or unauthorized disclosure of the data can result in both civil and criminal penalties, and in administrative penalties at USNA.

4. Monitor his/her student-researcher to confirm that his/her use of the human subject data is proper and within the parameters of the approved project, and that he/she is adequately safeguarding and protecting the confidentiality of the data.

5. Monitor the project of his/her student-researcher to confirm that the level of risk within the project has not changed from that described in the protocol submitted to and endorsed by the Academy's IRB and subsequently approved by the Superintendent. In addition, the faculty mentor must monitor the project to ensure that voluntary participation and withdrawal policies of human subjects in the project and all informed consent procedures are being followed and are being managed without any undue influence from the student-researcher.

6. Report any unexpected or adverse events, with respect to the human subjects in the project: to the department chair, to the appropriate Division Director or Senior Leadership Team member, to the Director of the Academy's HRPP office, and to the Chair of the Academy's IRB.

c. When human subjects or data about human subjects are used in research projects or Trident Scholar Program projects conducted by midshipmen, the student-researcher midshipman **and** his/her faculty mentor(s) jointly must satisfy the following requirements:

1. Submit a research proposal to the chair of the midshipman's academic major department for an evaluation of the scientific merit of the proposed project. The evaluation of scientific merit must be completed before the research protocol will be reviewed by the Academy's IRB. Additional information on the evaluation of scientific merit is available in Section XI of this policies and procedures manual.

2. Obtain written notification of the results of the Academy's IRB review and the subsequent approval decision on the protocol by the Superintendent before selecting project participants, distributing any informed consent forms, beginning any data collection activity on the project, etc., and/or before distributing any human subject datasets to any research collaborators.

3. Comply with all policies and procedures in this manual and in related USNA and SECNAV instructions, directives and notices that apply to human subject research projects conducted at the Naval Academy, at a non-USNA site but with USNA personnel, or in collaboration with non-USNA researchers at other locations.

4. Complete all required human subject research training before starting any participant selection, data collection, or data analysis on a project endorsed by the Academy's IRB and subsequently approved by the Superintendent. (Additional guidance on the education and training of persons conducting human subject research or working with data about human subjects can be found in Section V of this policies and procedures manual.)

d. In all cases, it is expected that the methodologies used in projects, surveys and focus groups involving human subjects and/or the data about human subjects follow accepted scientific practices, that the proposed projects have scientific merit, and that appropriate precautions are taken throughout all of the activities of the project to minimize the risks to the human subject participants and to safeguard and protect the data about the human subjects.

15.4 Responsibilities of the Division Directors and Members of the Senior Leadership Team

Division Directors and members of the Senior Leadership Team (SLT) must remain cognizant of the contents of this entire document. Specific information about the roles and responsibilities of Division Directors and members of the Senior Leadership Team are detailed in Sections VII and XI of this policies and procedures manual. In particular, Division Directors and members of the Senior Leadership Team are responsible for:

a. Ensuring that each research activity in his/her division, office or center that involves human subjects as participants or that directly or indirectly involves data about human subjects has been reviewed via the Academy's IRB process described in this policies and procedures manual and that a written notification of the IRB's endorsement and the Superintendent's

subsequent approval of the project, has been obtained by the principal investigator prior to the start of any activity on the project.

b. Ensuring that appropriate protections for the human subjects participating in a research protocol or a classroom- or laboratory-based project or demonstration are in place (prior to any participation selection, data collection and/or data analysis activity on the project) within his/her division, office or center for all human subject research projects endorsed by the Academy's IRB and subsequently approved by the Superintendent.

c. Ensuring that appropriate protections are in place within the division, office or center for the data about human subjects during an approved project. This includes protections while the data are collected, provisions for the safeguarding of the data once it has been collected, and during the data analysis phase of the project. Particular attention must be paid to the secure storage of the data and the restrictions in access to the data by anyone other than the project co-investigators.

d. Ensuring that all research investigators in his/her division, office or center who are planning a project that will directly or indirectly involve human subjects and/or the data about human subjects complete the required human subject research training before starting any data collection and/or data analysis on an approved project. (Additional guidance on the education and training of persons conducting human subject research or working with data about human subjects can be found in Section V of this policies and procedures manual.)

e. Ensuring the completion, by the principal investigator's immediate supervisor, of the required "Evaluation of Scientific Merit" on each proposed human subject research project to be carried out by an organizational unit or personnel under Division Director's or SLT member's cognizance. Additional information regarding the required evaluation of scientific merit can be found in Section XI of this policies and procedures manual. (The evaluation of scientific merit must be completed before the research protocol will be reviewed by the Academy's IRB.)

f. Ensuring that all reports of unexpected or adverse events, with respect to the human subjects, and/or all irregularities with respect to the collection, handling and storage of data about the human subjects in a project conducted in his/her division, office or center, are forwarded promptly to the Director of the Academy's HRPP office and to the Chair of the Academy's IRB.